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| 10/599,352      | 10/18/2007  | Peter Kenneth Graham | FPHCR.000GEN        | 7270             |

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| EXAMINER |
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LEE, SI M

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| ART UNIT | PAPER NUMBER |
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3775

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

01/23/2012

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/599,352             | GRAHAM ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | SI LEE                 | 3775                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 1-11 and 14-16 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1-11 and 14-16 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

1. This Office Action is responsive to the amendment filed on 11/21/20. As directed by the amendment: Claims 1, 3, 4, 10, 14, and 15 have been amended. Claims 12 and 13 were cancelled. Claims 1-11 and 14-16 are presently pending in this application.

#### ***Claim Objections***

2. Claim 7 is objected to because of the following informalities: The phrase "said gases transport means" in line 3 lacks antecedent basis and should be re-written as -- said gases transport conduit--. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

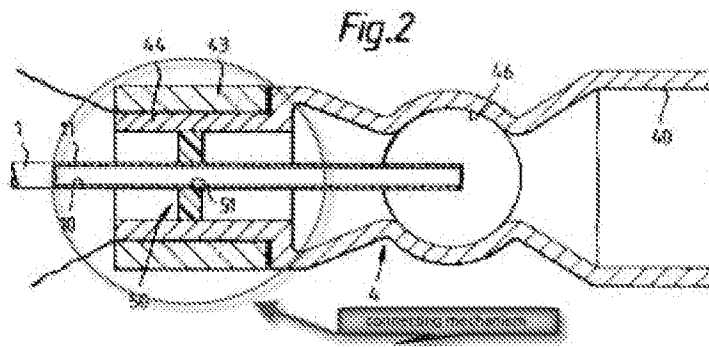
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al. (5,779,687) herein referred to as Bell, in view of Coles et al. (5,513,628) herein referred to as Coles, and further in view of Russo (6,923,184).

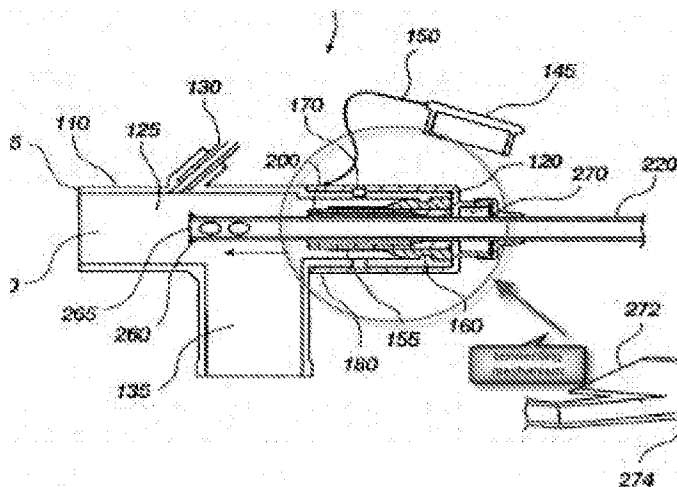
Regarding claim 1, Bell discloses a ventilating and aspirating system (see figure 1) having a gases transport conduit (side ports 45, 46) adapted to convey pressurized gases in use to a patient (column 3 lines 54-57). Bell discloses a ventilating and aspirating system (see figure 1) having a patient connector (41) adapted to deliver the pressurized gases through a tracheostomy tube fitting and the patient connector

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adapted to be in fluid communication with the gases transport conduit (45, 46) in use (figure 1 and column 4 lines 16-18). Figures 1 and 2 of Bell show a substantially tubular catheter mount (4) being fitted between the patient connector (41) and the gas transport conduit (45, 46) and having a passageway (extending between elements 44 and 40, see figure 2 of Bell) for receiving an aspirating system. Figure 1 of Bell further shows a suction tube (1) having a distal end and a proximal end, the suction tube (1) being surrounded by a collapsible envelope (2) (flexible, protective sleeve 2, see column 3, lines 16-19) and that the distal end of the tube fitted with a distal connector (33). In column 4, lines 24-26, Bell states that user grips the catheter (1) through the sleeve (2) and pushes it forwardly so that the distal patient end of the catheter is advanced through the connecting member (4) (the proximal end of the suction tube being movable through a proximal connector 43 attached to the envelope). Bell in column 3, lines 42-45, discloses that the proximal connector (43) is releasably connected to the catheter mount (4) (the proximal connector 43 is screwed onto a threaded proximal extension 44 of the connecting member). Furthermore, Bell in figure 2 further shows that the passageway being covered by a seal 50.



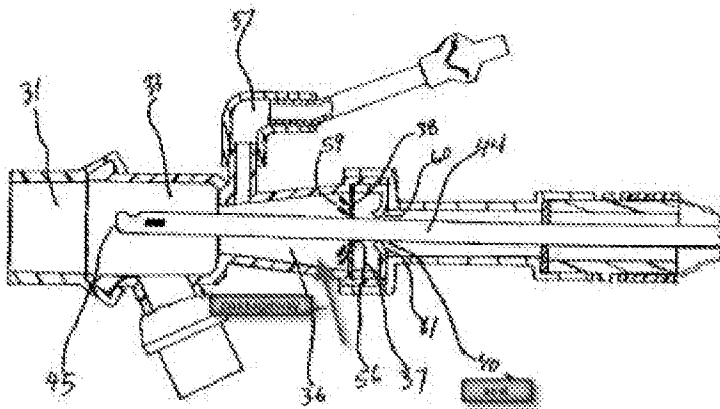
Bell differs from the present invention in that Bell's catheter mount lacks a re-sealing mechanism and proximal connector (43) lacks a piercing member. However, Coles teaches a ventilating and aspirating system having a catheter mount (105) for connecting with a proximal connector (185), a re-sealable seal (155) (figures 4-6) being located inside the catheter mount (105), the proximal connector having a piercing member (200), and the suction tube is capable of passing through the piercing member (200) and not contacting the seal, see figure 4 of Coles. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bell's catheter mount and proximal connector with a seal having re-sealable mechanism within the catheter mount and a proximal connector having a piercing member as taught by Coles, since such a modification would provide an alternative connection mechanism and control and guidance when the connector and catheter mount are joined together.



Yet, the modified Bell's device further lacks a seal located on an outer edge of the passageway. However, Russo teaches a seal 40 located on an outer edge of the

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passageway shown in figures 6 and 7. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the modified Bell's seal to be located on an outer edge of the passageway as taught by Russo, since such a modification would provide immediate piercing of the seal by the piercing member when the connector and catheter mount are joined together.



Regarding claim 2, the modified Bell's device has a chamber abutting an outer surface of the seal (40 of Russo) and an outer surface of the piercing member (200 of Coles) and creating a dead space within (figure 4 of Coles).

Regarding claim 3, the modified Bell's device has a proximal connector (180 of Coles) and a catheter mount (110 of Coles) connected. The adjacent surfaces on the proximal connector and the catheter mount abut to form a seal (40 of Russo). When connected, gases are substantially prevented from exiting to the atmosphere (figure 4 of Coles).

Regarding claim 4, the modified Bell's device has the catheter mount (110 of Coles) and the proximal connector (180 of Coles) releasably connected with a bayonet fitting (see figures 1 and 4 of Coles).

Regarding claim 5, the modified Bell's device has the seal (40 of Russo) made of an elastomeric material (column 7 lines 36-39 of Russo). The seal is capable of providing a substantially airtight seal because the seal is airtight until pierced by the piercing member.

Regarding claim 6, the modified Bell has the seal (40 of Russo) that includes a perforation (slit, see figure 7 of Russo). Figures 6 and 7 of Russo show that the slit allows for the piercing of the seal by the piercing member (44 - catheter). The modified Bell's device is capable of resealing the passageway once the proximal connector (180 of Coles) is detached from the catheter mount (110 of Coles).

Regarding claim 7, the modified Bell's device has the gases transport conduit (45, 46 of Bell) which may leak through the seal (40 of Russo) once pierced and then contained within the dead space (figure 4 of Coles).

Regarding claim 8, the modified Bell's device has the catheter mount (110 of Coles) allowing the suction tube (220 of Coles) through and entering the tracheostomy fitting (42 - trach tube of Bell, see figure 1) without the suction tube (220 of Coles) contacting the internal walls of the catheter mount (110 of Coles) (figure 4 of Coles).

Regarding claim 9, the modified Bell's device has the proximal connector (180 of Coles) which includes a washer (230 – wiper seal of Coles) to wipe the suction tube (220 of Coles) when removed (column 8 lines 59-62 of Coles).

Regarding claim 14, the modified Bell's device has a catheter mount having at least three passageways such that a first (opening at element 4) of the at least three passageways being adapted to be connected to a patient connector (42 of Bell), a

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second of the at least three passageways being adapted to be connected to a gases transport means (45 of Bell), and a third (opening at element 44 of Bell) of the at least three passageways being covered by a seal (40 of Russo) where the seal is located on an outer edge (figures 6 and 7 of Russo) of the third passageway and including a re-sealing mechanism, and being adapted to receive an aspirating system (figure 1 of Bell). The modified Bell's device has the catheter mount being adapted to be fitted in use between the patient connector (42 of Bell) and the gases transport means (45 of Bell).

5. Claims 10, 11, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell (5,779,687) in view of lund et al. (5,598,840), herein referred to as lund, and further in view of Kee et al. (5,309,902), herein referred to as Kee.

Regarding claim 10, Bell discloses a tube (1) having a distal end and a proximal end, a collapsible envelope (2) surrounding the tube (1), a distal connector (33) fitted to the distal end and adapted to allow the distal end of the suction tube (1) to be connected to a suction means (6) in use, and a proximal connector (43) attached to the envelope (2) that the proximal end of the tube (1) is moveable through shown in figure 1. Bell in column 3, lines 42-45, discloses that the proximal connector (43) is releasably connected to the catheter mount (4) (the proximal connector 43 is screwed onto a threaded proximal extension 44 of the connecting member).

Bell lacks an integrally formed piecing member, a proximal end of the piercing member defining a most proximal point of the proximal connector where the piercing



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member is capable of piercing a seal of the catheter mount. However, lund teaches a ventilating and aspirating system having a catheter mount (105) for connecting with a proximal connector (185), a re-sealable seal (155) (figures 1 and 4) being located inside the catheter mount (105), the proximal connector having an integrally formed piercing member (200), and the suction tube is capable of passing through the piercing member (200) and not contacting the seal, see figure 4 of lund. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bell's connection between the catheter mount and proximal connector with a connector adapted to be releasably connect to the catheter mount having an integrally formed piercing member as taught by lund, since such a modification would provide an alternative connection mechanism and the ability to immediately pierce a seal when the connector and catheter mount are joined together.

Next, lund's connector shown in figure 11 further lacks a proximal end of the piercing member defining a most proximal point of the proximal connector. However, figure 4 of Kee teaches a piercing member 41 having a most proximal point on the connector 20. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the modified Bell's piercing member (figure 11 of lund) with a piercing member 41 having a most proximal point as taught by Kee, since such a modification would decrease the suction tube's movement inside the piercing member of the catheter mount when ventilation is provided. The modified Bell's device has the suction tube capable of passing through the piercing member and not contacting the seal (figure 4 of lund).

Regarding claim 11, the modified Bell's device has a chamber abutting an outer surface of the seal (155 of lund) and an outer surface of the piercing member (200 of lund) and creating a dead space within (figure 4 of lund).

Regarding claim 15, the modified Bell's device has an outer cup shaped fitting (figure 11 of lund), an inner cup shaped fitting (figure 11 of lund), nested within the outer cup shaped fitting, and a piercing member nested within the inner cup shaped fitting and integrally formed with the outer shaped cup fitting (figure 11 of lund) and adapted to pierce a seal (155 of lund). The modified Bell's device has the piercing member extending beyond the rim of the outer cup shaped fitting (figure 4 of Kee). Figure 1 of Bell shows a first end of the catheter tube connector being adapted to be in communication with a suction system. The modified Bell's device has a second end of the catheter tube connector being adapted to be releasably connected to a catheter mount passageway covered by a seal (155 of lund) such that the rim of the inner cup shaped fitting abuts an end of the catheter mount passageway and the piercing member (figure 11 of lund) adapted to allow a suction tube to pass through the piercing member and into the catheter mount passageway without the suction tube contacting the seal (155 of lund) (see figure 4 of lund).

Regarding claim 16, the modified Bell's device has the outer cup shaped fitting that is a releasable lockable bayonet fitting shown in figures 1 and 4.

***Response to Arguments***

6. Applicant's arguments filed 11/21/11 have been fully considered but they are not persuasive.

Applicant argues on pg 6, paragraph 5 lines 1-5, and pg 9, paragraph 2 lines 1-4, of the remarks that Bell nor Coles teaches a seal located on an outer edge of the passageway that receives the aspirating system in which examiner agrees. However, the reference Russo is used to teach this feature. See Office Action above.

Applicant argues on pg 7, paragraph 2 lines 1-7, and pg 8, paragraph 1 lines 1-14, of the remarks that there is no motivation to combine Bell and Coles. Yet, the combination of Bell and Coles would provide an alternative connection mechanism and control and guidance when the connector and catheter mount are joined together and able to quickly remove the assembly after patient use. The reseal mechanism would prevent further contamination to the user after the removal of the aspirating assembly.

Applicant discusses on pg 8, paragraph 3, lines 1-4 of the remarks on the claim limitation submitted in the amended claims "a proximal end of said piercing member defining a most proximal point of said proximal connector". The combination of the references of Bell, lund, and Kee is used to teach this limitation.

***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fangrow, Jr. (2006/0212000) and Carlsen et al. (2004/0255952) are cited to show seals located on an outer edge of a passageway.

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8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SI LEE whose telephone number is (571)270-5450. The examiner can normally be reached on Monday-Friday 8:30am-6pm, working alternating Friday's.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SI LEE/  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
Supervisory Patent Examiner, Art  
Unit 3775